

**REMARKS/ARGUMENTS**

As an initial matter, Applicants wish to thank the Examiner for indicating claims 33, 34, 64, 74, and 82 as allowable in the Office Action dated September 29, 2003 (Office Action at 7).

I. Status of the Claims

By the present amendment, originally presented claims 1-102 have been cancelled without prejudice or disclaimer and new claims 103-223 have been added. Support for the present amendment may be found in the specification as originally filed, including the original claims. Therefore, no new matter has been added.

New claims 103-166 incorporate the subject matter of original claims 33, 34, 64, 74, and 82, indicated as allowable in the Office Action. These new claims, with the corresponding original claims indicated as allowable, are shown in the following table.

New Claims	Support
103, 104 and claims dependent therefrom*	Original Claim 33
140 and claims dependent therefrom*	Original Claim 64
158 and claims dependent therefrom*	Original Claim 74

\*The dependent claims correspond to original dependent claims 4-53 and 55-102.

Additionally, new claims 167-223 have been added. As recited in new claims 167-223, the rate of irradiation not constant and comprises a rate of between 0.1kGy/hr to 3.0kGy/hr for at least a portion of the period of irradiation and a rate of at least 6.0kGy/hr for at least

another portion of the period of irradiation. Support for this limitation may be found in the specification as originally filed, for instance, paragraphs 58 through 65. The undersigned notes that this limitation is the same as that recited in independent claim 1 of U.S. Patent No. 6,682,695, which issued from U.S. Patent Application No. 10/197,248.

II. Response to the Grounds of Rejection

In the outstanding Office Action, the Office made the following grounds of rejection:

- A) Claims 54, 65, and 65 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,981,163 to Horowitz et al. (“Horowitz et al.”);
- B) Claims 1, 8-11, 28-32, 35, 36, 38-41, 43-49, 53, 75-81, 83-94, and 96-101 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Horowitz et al. in view of U.S. Patent No. 6,171,549 to Kent;
- C) Claims 2-7, 17-32, 35, 36-42, 50-52, 75-81, and 102 are rejected 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,730,933 to Peterson (“Peterson”) in view of Horowitz et al.; and
- D) Claims 1 and 12-16 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,989,498 to Odland in view of Horowitz et al.
- E) Claims 56-63, 66-73, and 95 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Horowitz et al. in view Peterson.

Applicants respectfully traverse these rejections, and respectfully submit that the

rejections are moot for at least the following reason. Originally presented claims 1-102, as discussed above, have been cancelled. New claims 103-166 have been added, which encompass the subject matter indicated as allowable by the Examiner, i.e., original claims 33, 34, 64, 73, and 82. Since these claims recite subject matter indicated as allowable in the Office Action, the prior art of record fails to teach or to suggest the invention as recited in new claims 104-166 for at least the reasons noted by the Examiner in the Office Action with respect to original claims 33, 34, 64, 73, and 82 (Office Action at 7). Therefore, these grounds of rejection should be withdrawn.

Regarding new claims 167-223, the undersigned respectfully submits that the prior art of record fails to teach or to suggest methods for sterilizing biological materials, as presently claimed, wherein the rate of irradiation is not constant and comprises a rate of between 0.1kGy/hr to 3.0kGy/hr for at least a portion of the period of irradiation and a rate of at least 6.0kGy/hr for at least another portion of the period of irradiation. Therefore, for at least this reason, new claims 167-223 are allowable over the prior art of record.

As indicated above, this limitation, *viz.*, the rate of irradiation is not constant and comprises a rate of between 0.1kGy/hr to 3.0kGy/hr for at least a portion of the period of irradiation and a rate of at least 6.0kGy/hr for at least another portion of the period of irradiation, is the same as that recited in independent claim 1 of U.S. Patent No. 6,682,695 which issued from U.S. Patent Application No. 10/197,248. As noted by the Examiner in that related application, the prior art fails to teach or to suggest methods for sterilizing

biological materials wherein the dose rate is increased during the course of irradiation (see U.S. Patent Application No. 10/197,248, Office Action dated July 7, 2003). Therefore, new claims 167-223 are allowable over the prior art of record for at least this reason.

III. Information Disclosure Statement

Applicants respectfully request that the Examiner consider the references cited on the PTO-1449 forms, submitted with the Information Disclosure Statement filed September 26, 2003, and initial and forward the forms with the next official U.S. Patent and trademark Office communication.

**CONCLUSION**

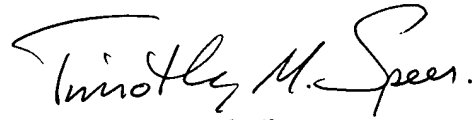
In view of the foregoing amendments and remarks, it is respectfully submitted that the application is in condition for allowance. If the Examiner believes that any additional changes would place the application in better condition for allowance, the Examiner is invited to contact the undersigned agent, Timothy M. Speer, at the telephone number listed below. Favorable consideration and prompt allowance are earnestly solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this, concurrent and future replies, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Serial No. 09/960,701  
Reply to Office Action of September 29, 2003

Docket No. CI-0008

Respectfully submitted,  
FLESHNER & KIM, LLP

A handwritten signature in black ink that reads "Timothy M. Speer." The signature is fluid and cursive, with the first name "Timothy" and last name "Speer" clearly legible.

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**Date: March 1, 2004**

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